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(54) Abstract Title
An analyte testing system including a test strip

(57) A device for detecting an analyte in a sample by a physically detectable reaction with a reagent comprises: a set of test strips 11 holding a test pad 12 impregnated with the a reagent and having a handle 14 extending from the surface of the strip opposite to the pad, the handle containing a channel 10 for transferring the fluid sample 16 to the pad; calibration means having calibration information relating to the reagent on the test strips *eg* a master test strip or a memory chip; a housing having a docking portion to receive part of a test strip; a sensor in the housing producing an electrical signal in response to reaction of the sample and reagent; and a processor in the housing operating in accordance with the calibration means and the sensor signal to generate an output signal related to the analyte present in the sample. The strip may have a locating projection on face 15.

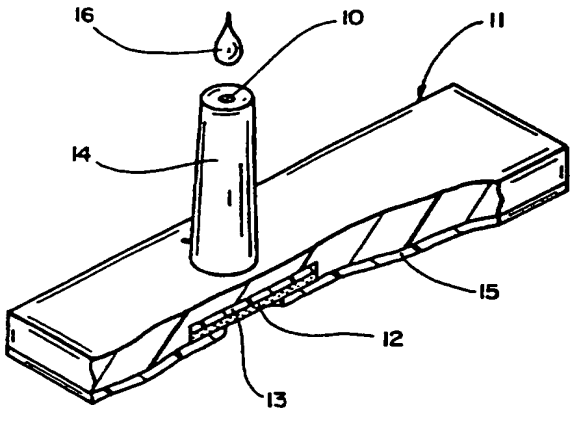

FIG_1A

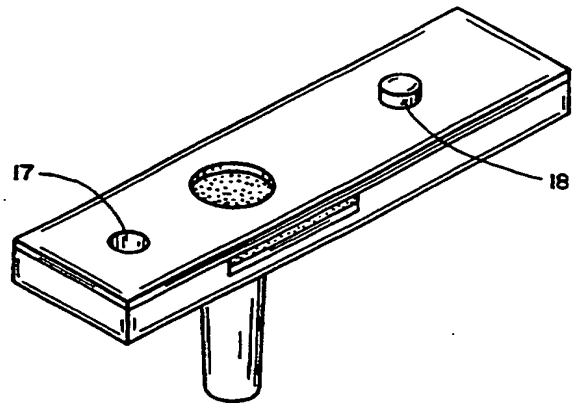

FIG_1B

The search under Section 17 was carried out in respect of the amended claims filed in response to an objection under Section 76(1).

The date of filing shown above is that provisionally accorded to the application in accordance with the provisions of Section 15(4) of the Patents Act 1977 and is subject to ratification or amendment.

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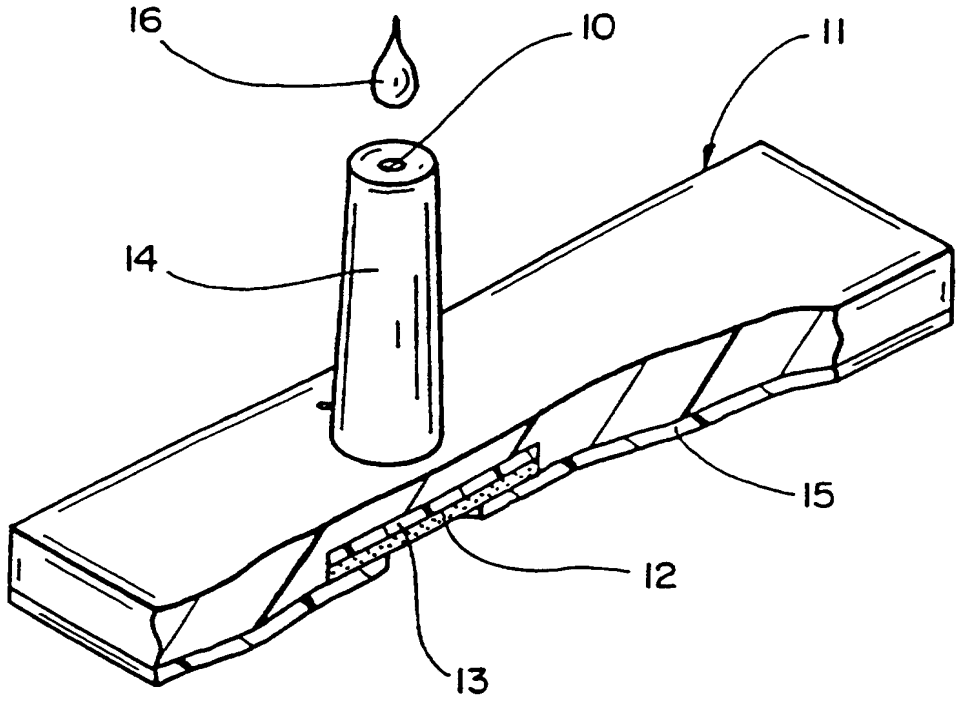

FIG_1A

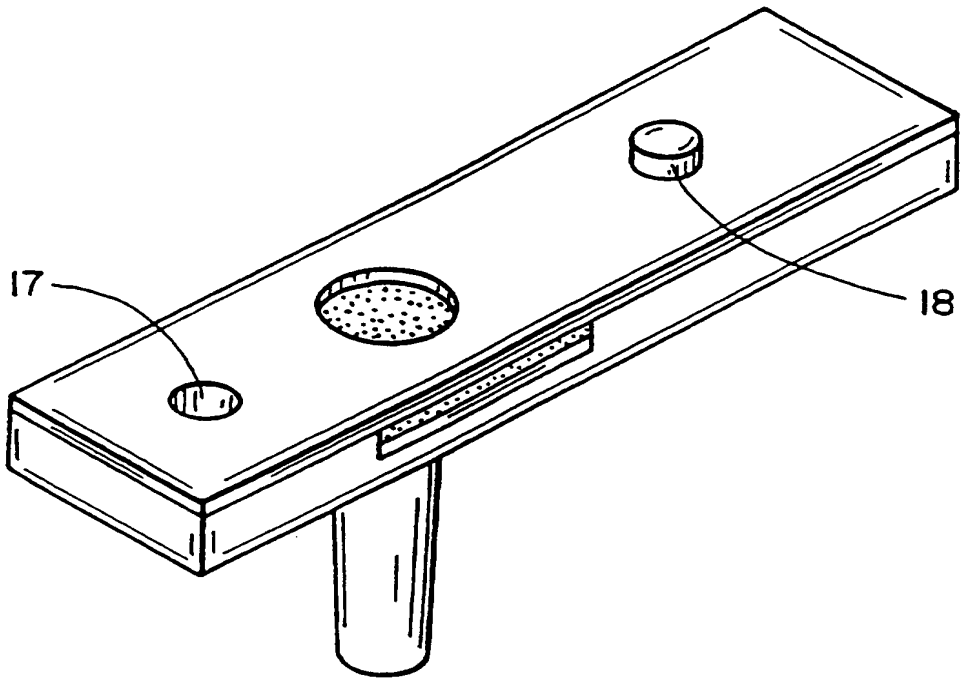

FIG_1B

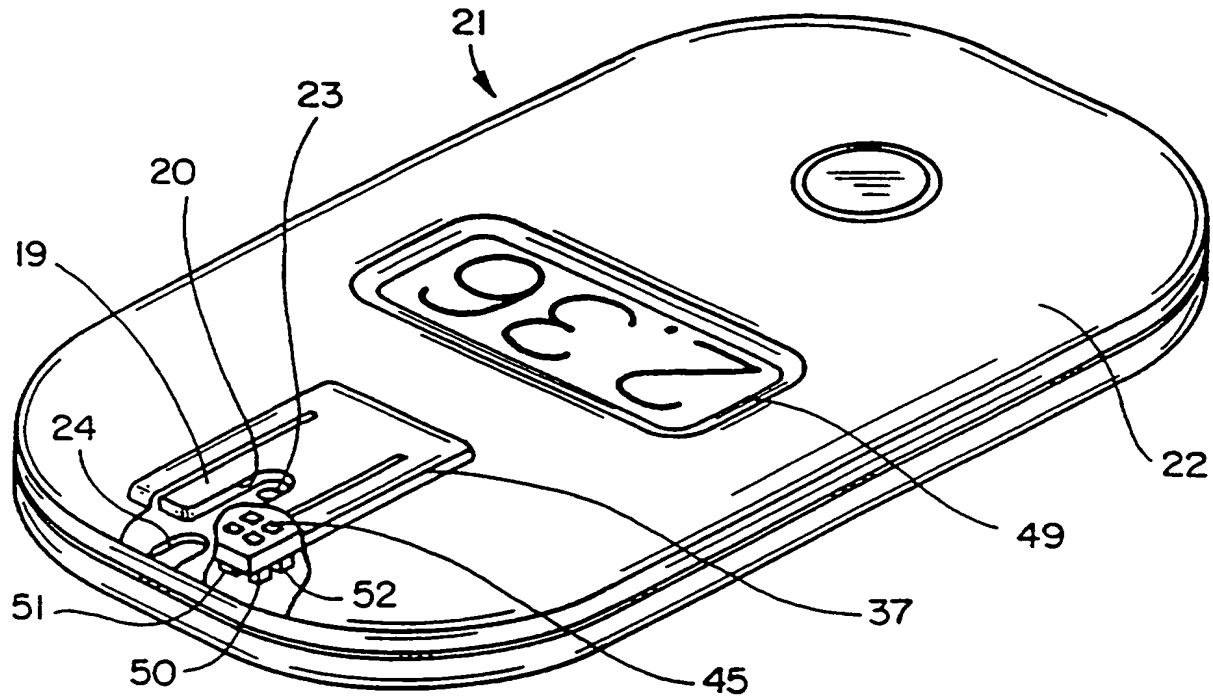

FIG_2

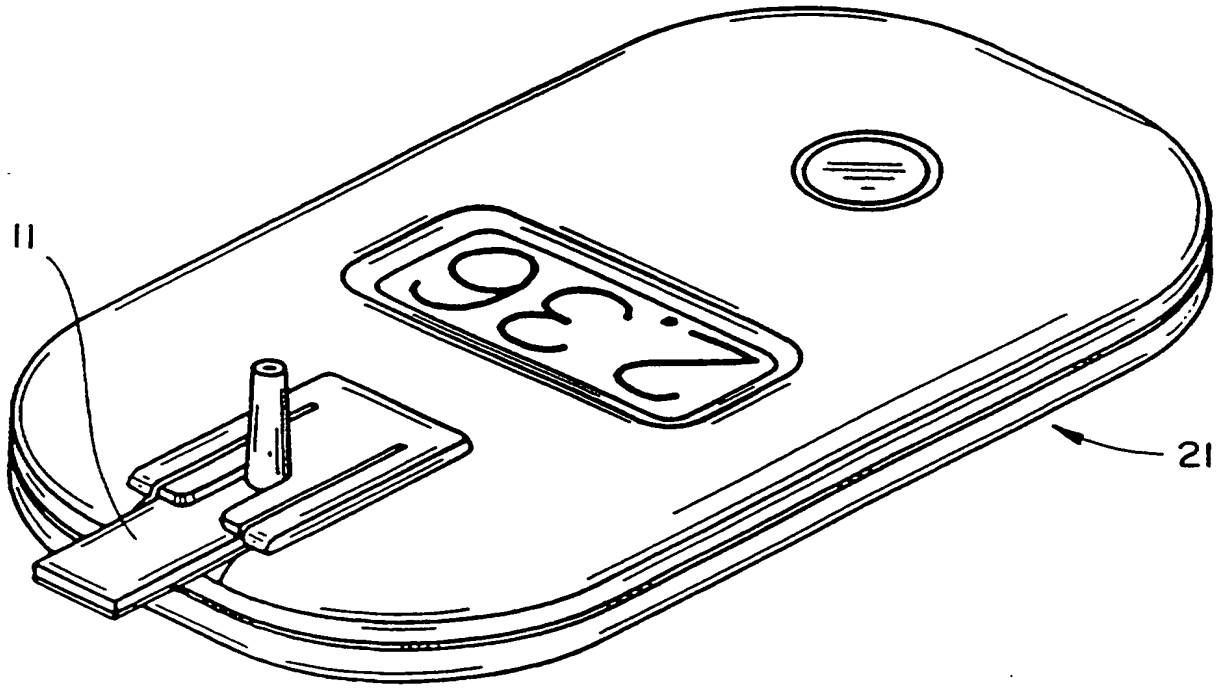

FIG_3

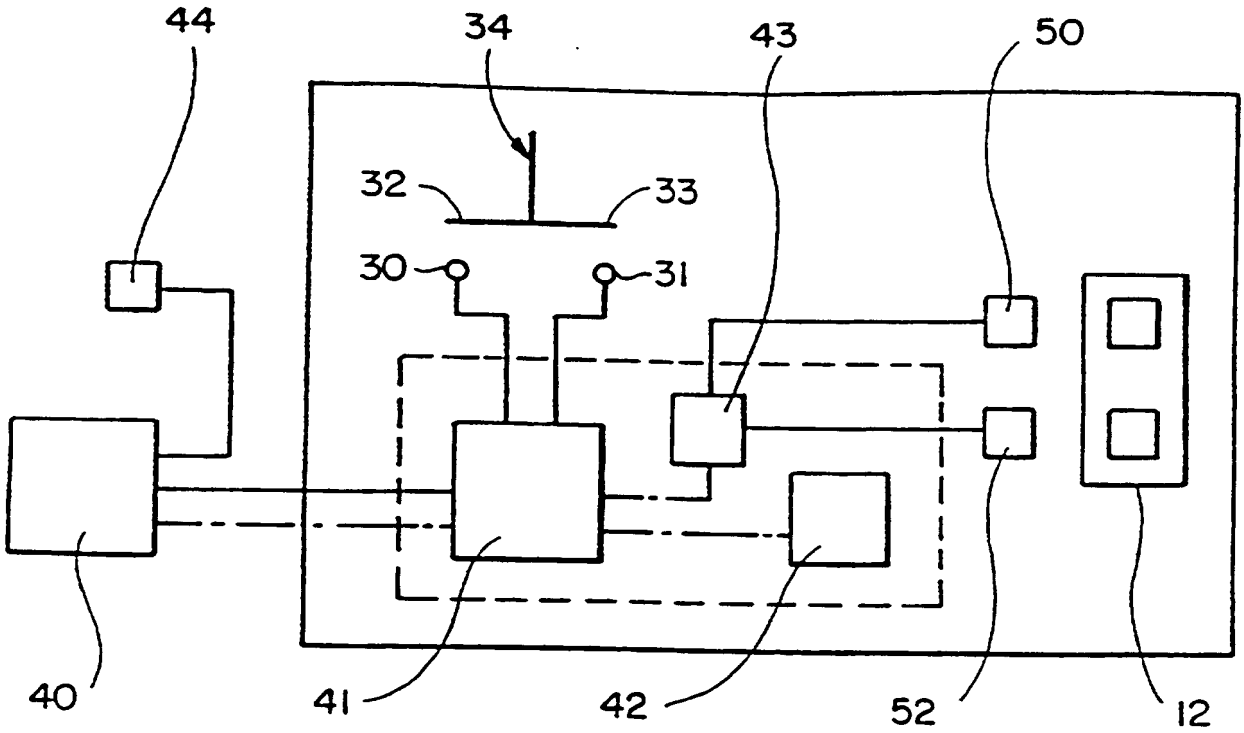

FIG_4

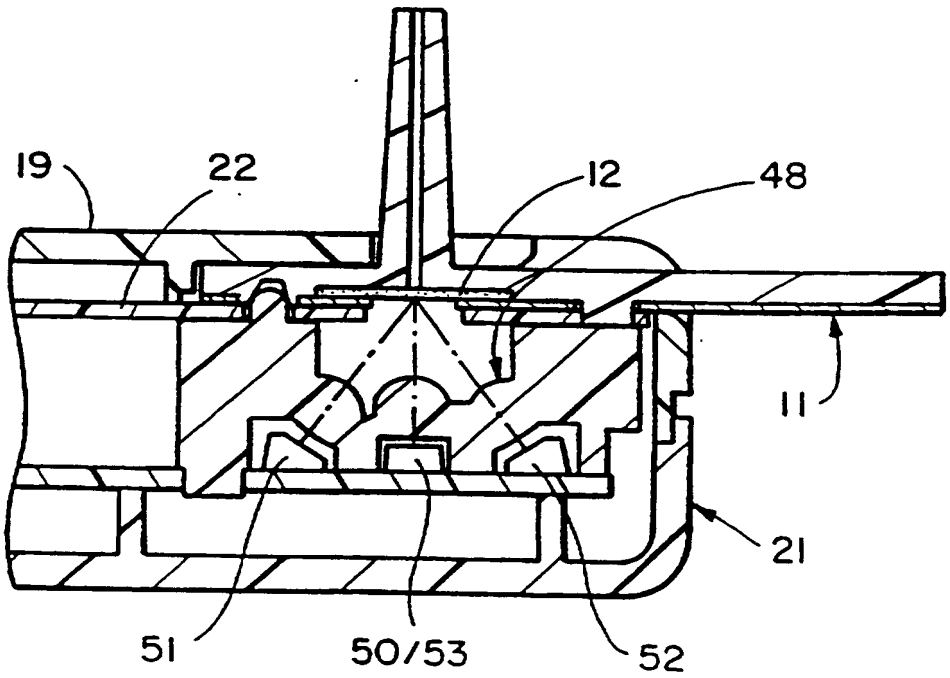

FIG_8

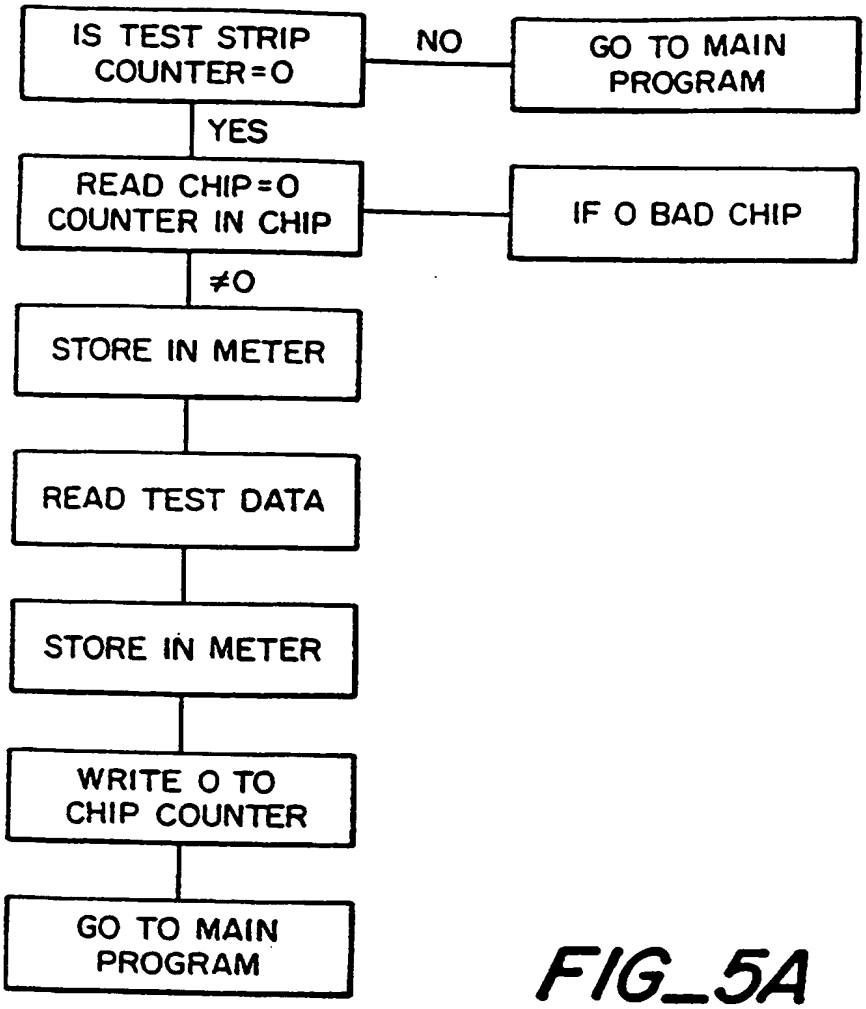

FIG_5A

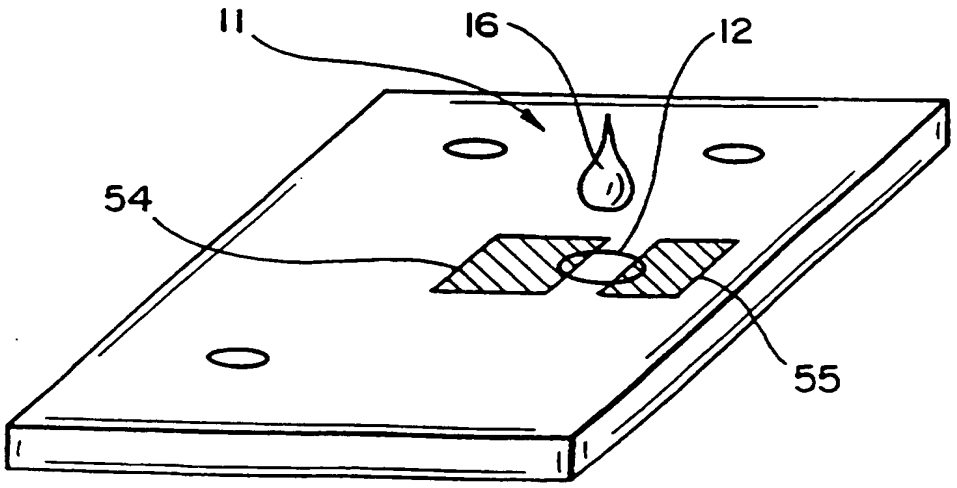

FIG_5B

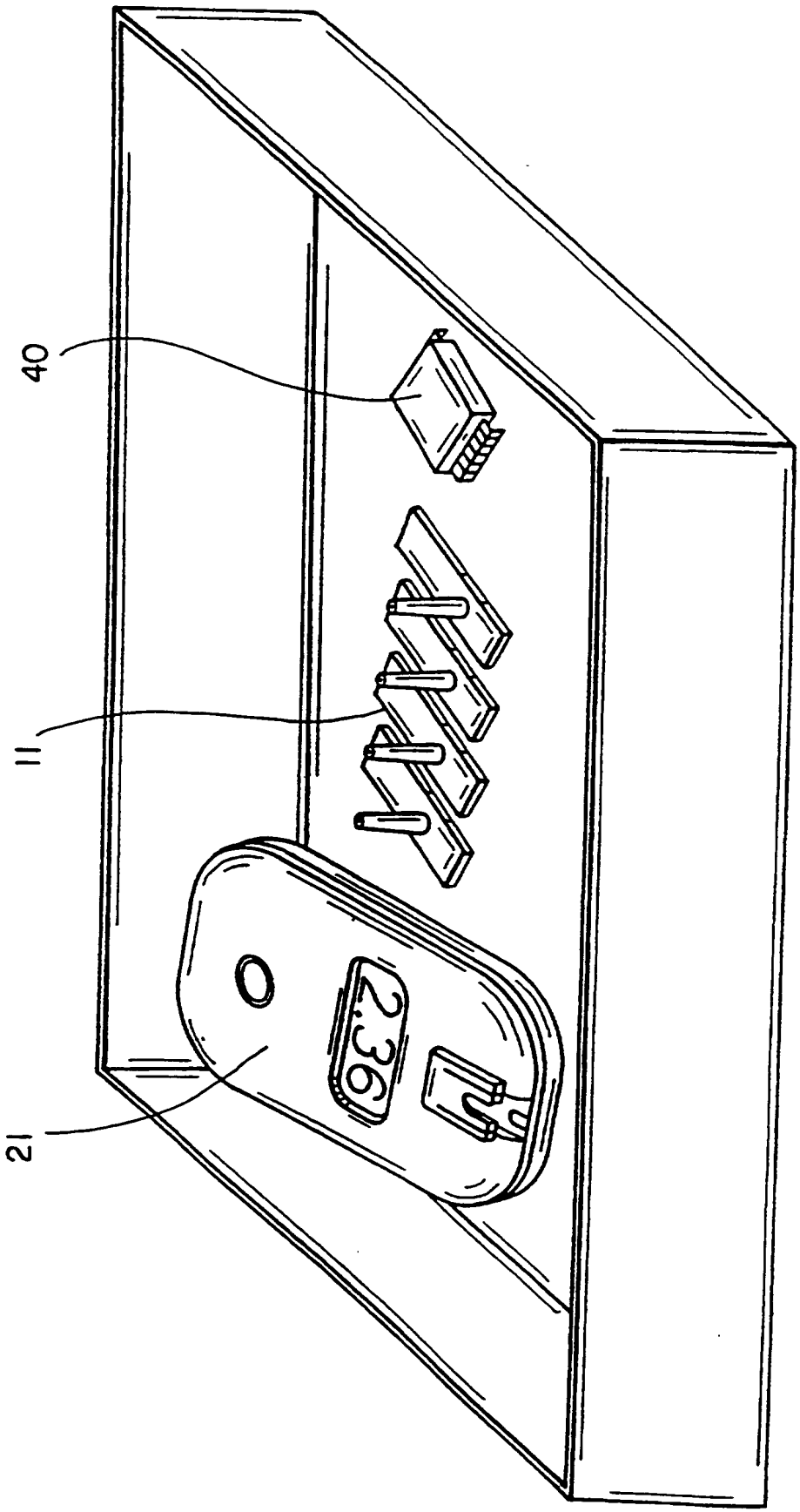

FIG_6

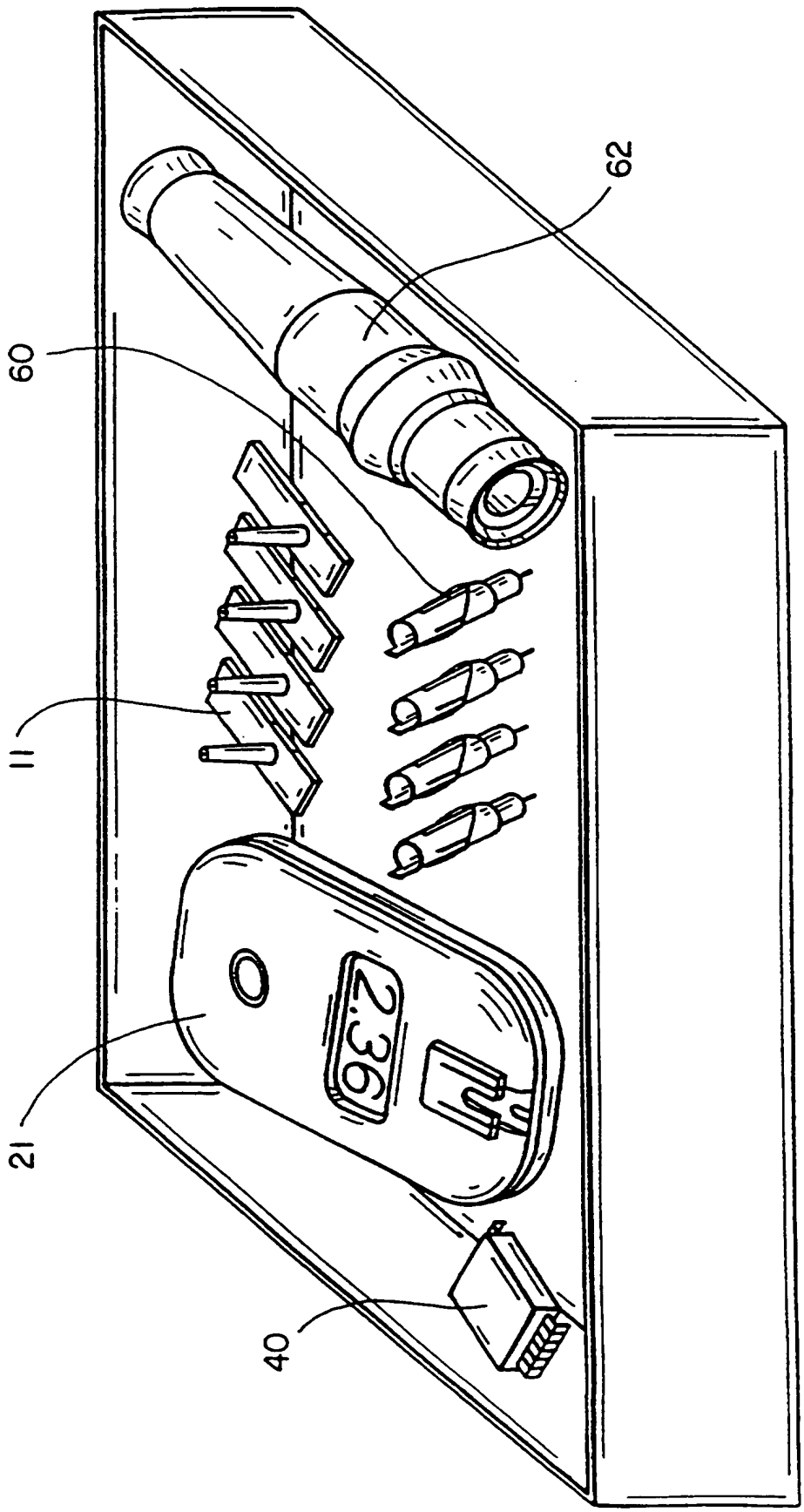

FIG_7

TEST STRIP

The present invention relates to a test strip for use with a detection device for determining the presence or concentration of analytes or biological agents in a sample.

The need for simple methods to determine the chemical and biological constituents in bodily fluids has increased as point of care testing has gained in popularity. A common application is the self monitoring of blood glucose concentrations by patients with diabetes. These patients frequently administer insulin or take other therapeutic actions based on the test results. As testing is generally recommended multiple times daily and may occur in any setting, an easy to use and relatively inexpensive method to accomplish this task is required. The costs of testing are significant to many diabetic patients, especially elderly patients with fixed incomes and those who are not reimbursed by health insurance plans.

In addition to chronic disease monitoring, there are other applications where simple, low cost testing at the point of care may be desired. For example, many practitioners believe that certain medications could be administered much more effectively, both from a medical outcomes and from a cost perspective, if the circulating level of such medications could be monitored during the course of treatment. Generally, if the level of an analyte or

biological agent is important enough, the patient needs to go to a clinic or laboratory and submit to a venipuncture so a test may be run on an expensive clinical instrument. The ability to inexpensively monitor the patient either in the doctor's office or at home could lead to improved outcomes. Given the current pressures on improving the cost effectiveness of health care, inexpensive, easy to use alternatives to expensive test methods would be welcomed.

The National Institutes of Health conducted a large scale study to evaluate the benefit of long term tight control of the blood glucose for the diabetic patient. The study, known as the DCCT, proved that long term tight control of the blood glucose levels in patients had a direct relationship to the health of the patient. One way for the medical profession to monitor the control of a patient is for the patient to use a blood glucose monitoring system which has a memory unit to record the blood glucose level and other data such as date and time.

Many diabetics currently use a test method described in U.S. Patent No. 5,304,468 to Phillips et al. This system is comprised of an electronic meter and a disposable reagent strip. The meter reads the color change of the strip which correlates to the concentration of the analyte in the sample applied to the strip. The meter is an expensive and complex instrument which uses multiple light sources or detectors to isolate the reagent color change from the sample color. The user must select the calibration code for the meter to match the calibration code of the test strips. In this way, the meter accommodates a wide range of test strip performance values.

U.S. Patent No. 4,637,403 to Garcia et al. describes an integrated system which provides a method by which the patient lances the finger to get a sample of blood which is then used by the device to read the quantity of analyte in the sample. This system uses a complex reflectance system to read the

analyte level in the sample.

U. S. Patent No. 5,279,294 to Anderson et al. describes a hand held shirt pocket device for quantitative measurement of glucose or analytes in biological fluids. The device has a sophisticated electronics system and a sampling system integrated into one device to determine the quantity of analyte in a bodily fluid sample

U.S. No. Patent 5,515,170 to Matzinger et al. describes the difficulties of keeping a strip holder and optics system clean and the need to present the test strip in the proper perspective to the optics.

European Patent Specification 0 351 891 B1 Hill et al. describes an electrochemical system and electrodes which are suitable for the *in vitro* determination of blood glucose levels. The system requires the use of expensive electrodes and a sophisticated reader to determine blood glucose levels.

U.S. Patent No. 4,994,167 to Shults et al. describes a measuring device for determining the presence and amount of a substance in a biological fluid using electrochemical methods. This system requires a complex instrument and method for the patient to determine the quantitative result.

U.S. Patent No. 5,580,794 to Allen et al. describes a single use disposable measuring device for determining the presence and amount of a substance in a biological fluid using reflectance methods. This system utilizes an optics and electronics package which are mated in a single plane.

Single use disposable devices have been designed for the analysis of analytes in bodily fluids. U.S. Patent No 3,298,789 to Mast describes a system in which whole blood is applied to a reagent strip. After a precise, user-timed

interval, the blood must be wiped off by the user. An enzyme system reacts with the glucose present in the sample to create a color change which is proportional to the amount of glucose in the sample. The strip may be read visually, by comparing to a printed color intensity scale, or in an electronic instrument.

U.S. Patent No. 5,418,142 to Kiser et al. describes a single use device which does not require blood removal or color matching. The amount of analyte present in the sample is read in a semiquantitative fashion.

U.S. Patent No. 5,451,350 to Macho et al. describes a single use system for the determination of an analyte in a biological sample.

U.S. Patent 5,522,255 to Neel et al. describes a fluid dose, flow and coagulation sensor for a medical instrument which uses a non-volatile electronic calibration device in the system to check the calibration of the reagent strip.

U.S. Patent No. 5,053,199 to Keiser et. al. describes an electronically readable information carrier for use with a medical device.

U.S. Patent No. 5,366,609 to White et. al. describes a biosensing meter with a pluggable memory key. This device uses a pluggable memory key which is used to control the operations of the meter.

U.S. Patent No. 5,307,263 to Brown describes a modular microprocessor based health monitoring system designed to collect data from a health monitoring test system such as a blood glucose monitoring meter.

Although many improvements have been made, the cost and complexity of measuring analyte levels in biological samples remains a significant issue for patients and for the health care system. Even patients who are covered for

blood glucose monitoring supplies must often purchase the meter and await reimbursement. The need to match the calibration of a meter and the strips or electrodes in use leads to errors in performance and adds cost and complexity for the manufacturers. The availability of a low cost, simplified quantitative test system for the periodic monitoring of constituents of biological fluids, such as glucose in blood, would make testing more accessible to patients and would improve their well-being and reduce the cost of their care.

Our co-pending British Application No. 9811645.2 from which the present application is divided overcomes the deficiencies of the prior art testing instruments by providing a low cost testing instrument which permits the packaging of the testing instrument and test strips together in a package, creating a synchronized system which may be used to perform a specific number of tests. The testing instrument is provided at no extra cost to the user, who benefits from having a fresh device with each new package of test strips purchased. This eliminates the need for the patient to make an investment in test equipment to monitor a specific condition or therapy.

In an alternate configuration disclosed in this co-pending application, the device is provided as part of a starter package including a sampling device and test strips. It is disclosed that replacement test strips can then be purchased separately without the device or sampler if longer testing instrument life is preferable. For example, the desire to include additional features such as data management capabilities could add cost which would favour a longer useful life for the testing instrument.

The testing instrument of our co-pending application incorporates a moulded lens optic system consisting of one or more channels and a simple electronics package consisting of light emitting diodes (LEDs), analog to digital conversion electronics, a processor unit, Read Only Memory and a digital display system. The testing instrument case has a positioning system which interfaces with the test strip to create positive location and alignment for the reagent test pad within the strip and the optics.

The applied bodily fluid reacts with the reagents impregnated in the test pad within the test strip and the resulting colour change is read by the optics system. The signal is converted and displayed on the digital readout as the concentration of the analyte in the sample.

A system which requires a smaller fluid sample would be attractive to many patients. There has been a trend toward smaller sample sizes, but most devices still require about 10 μL of blood. Many patients have difficulty routinely applying an adequate sample to the strips or electrodes. Inadequate sampling can cause erroneous results or may require that the user discard an expensive test strip and repeat the sample application procedure.

The present invention is directed to a test strip having an opening with a test pad positioned in the opening and impregnated with a reagent system for reading in the test instrument and a handle extending from the surface of the strip on the opposite side from the opening and containing a channel for transferring the fluid sample to the test pad.

The test strip according to the present invention is especially suited to use with the test instrument of our co-pending application.

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

Figures 1A and 1B are perspective views of an example of a test strip according to the present invention;

Figure 2 is a perspective view of a testing instrument in which the test strip of Figures 1A and 1B can be used;

Figure 3 illustrates the testing instrument of Figure 2 and a test strip of Figures 1A and 1B;

Figure 4 is a block diagram of testing instrument electronics and optics for reading the test strip;

Figures 5A and 5B illustrate a method of confirming the wetting of the test pad and contact to start the timing of the testing instrument;

Figure 6 shows a kit of the system including testing instrument and test strips;

Figure 7 shows a kit of the system including testing instrument, test strips and sampling devices;

Figure 8 shows the use of two detectors and two emitters in an optics system.

Figure 1 is a perspective view showing a test strip 11 in accordance with the invention, the test strip 11 comprising a test pad 12 and holder 13 for analysis of bodily fluid 16. The test strip 11 provides a handle 14 for the patient to hold the strip 11. The handle operates as a wick to transfer the bodily fluid 16 to the test pad 12 and is provided with a channel 10 for this purpose. The test pad 12 may be formed from bibulous matrix which has been impregnated with a reagent system comprised of enzymes, indicators and blood separation agents.

Test strip 11 is provided with an alignment mechanism which may comprise recess 17 and projection 18 disposed on bottom portion 15 of the test strip 11. These operate to insure positive location and orientation of the test strip 11 with respect to the testing instrument 21 of the invention by engaging corresponding portions of the testing instrument as explained below. Of course it is contemplated that other test strip configurations can be used with the system of the invention without patentable departure from the spirit and scope of the invention.

Figure 2 is a perspective view of testing instrument 21 which can be used to read test strip 11. The testing instrument 21 has a housing 22 which is provided with optics view window 23 and a docking portion 37 for mating with alignment recess 17 and projection 18 of test strip 11. Docking portion 37 may comprise a slot 20 disposed in a retaining clip 19 which operates to guide handle 14 of test strip 11 into position, along with a recess 24 to mate with projection 18 of the test strip 11. Proper alignment for accurate reading is thereby insured, as illustrated in Figure 3, which shows the testing instrument 21 in operational position in communication with the test strip 11.

Testing instrument 21 is also provided with a sensor 45 for measuring the analyte concentration in sample 16, along with a display 49 for displaying the result. The sensor 45 may be optical in nature, and as shown in Figure 8, may comprise paired light emitter and detector devices. Specifically, an LED emitter 50 and a photodetector 51 measure reflected light from the sample-containing test pad 12. This reflected light is proportional to the amount of analyte in the sample as manifested by the extent of reaction of the sample/analyte with the reagent on the test pad 12. Ambient light is blocked by a design of test strip 11 and testing instrument 21 which minimizes error induced by ambient light corrupting the reflectance reading. Such a design may include appropriately limiting the size view window 23 while selecting sufficiently opaque materials to form the material of the housing 22 from which view window is formed. Insuring proper alignment in accordance with the invention also serves to minimize ambient light corruption.

Numerous optical schemes may be employed, including use of transmitted rather than reflected flight, multiple LED/detector pairs and various arrangements thereof. It is also contemplated that various light source:light detector ratios may be used, departing from the one-to-one correspondence disclosed.

An LED 53 is also provided and corresponds with a photodetector 52. The photodetectors 51 and 52 may be selected to operate at different light intensity levels, such that light below or at a predetermined intensity threshold is measured by one photodetector, while light above the threshold is measured by the other photodetector. Alternatively, one detector can be used to measure reflectance of a particular colour component,

while the other measures the reflectance of a different colour component, or one detector can measure overall light intensity while the other ———————————

measures a color component. Also, a reference detector (not shown) could be employed to compensate for the deterioration of the LED intensity over time. In alternative arrangement, the measurement from one detector can be used to provide a compensation for hematocrit level or oxygen content of the blood. One of ordinary skill in the art will realize many modifications and remain within the purview of the invention.

An optical arrangement in accordance with the invention is further provided with a molded plastic lens system 48 to focus light to and from the sample on the test pad 12. Such an arrangement provides the capability of focusing the light to and from a small reaction area, which reduces the size of the test pad 12 and the amount of sample required to effect the testing procedure. Advantages thus realized include reduction in size/cost of the matrix employed and quantity of expensive reagents required.

The optics of the invention may include appropriate optical filtering to optimize measurement, or electronic filtering and masking techniques may be employed to improve signal-to-noise levels. An optical filtering scheme of the invention, when blood analysis is to be performed, involves the use of existing membrane materials with a blocking filler to create an opaque membrane which blocks interference from red blood cells and can assist in the separation of red blood cells from relatively clear fluid.

Another optical configuration uses multiple LED and photodetector pairs. A first pair is used to achieve the primary analyte determination. A second pair is used to monitor test initiation and to quantify hemoglobin and hematocrit. Subsequent pairs are used to monitor native color effects of lympic and icteric samples. Additional optical pairs are used in association with added chemical components in the strip for specific determination of possible interference factors such as pH, specific gravity, etc. as well as for specific determination of additional analytes such as cholesterol, triglycerides, etc.

Such analysis, possibly using different wavelengths, provides significant benefits to overcoming interfering effects from the sample and the environment. By selecting wavelength pairs which are tuned to detect components of the test, it is possible to isolate and quantify the analyte, hematocrit and red blood cell contributions in a testing event. In accordance with the invention, interference from the environment is minimized by separating its effects and monitoring each one independently using multiple optical systems. Through detection and quantification, the individual contribution to the measurement can be subtracted from the analyte measurement. With the ever decreasing cost of computing power, and a unique of constructing multiple optical systems at very low cost, the approach of the invention is readily applicable to home diagnostic use.

The test strip 11 is comprised of a test pad 12 situated in a test pad holder 13. This holder provides a means for accurately positioning the test pad 12 with respect to the sensor 45 in addition to providing a means for blocking ambient light from effecting the analysis. The test pad 12 is impregnated with the appropriate chemistry to permit a colormetric analysis of the analyte being tested and may therefore provide a stable absorbent substrate.

The test strip 11 of this invention differs from current test strips in multiple ways. For current test strips, the nonporous support provides a handle for the patient [U.S. Patent No. 5,526,120 Jina et al.], and/or a means of aligning the test strip in a strip holder [U.S. Patent No. 5,515,170 Matzinger et al.] The test strip of this invention does provide a support for the test pad. The strip positively seats on the testing instrument, assuring proper alignment. It also seals the optics area from ambient light and blood contamination. Thus it provides all of the functionality of a test strip and test strip holder of a conventional reflectance system. The test strip provides additional benefits in being removed after each test, facilitating easy access to the optics area for cleaning if required. With this combination part, the overall cost of the system is further reduced. When inserted into the detection device 21, the test strip 11

contacts complete a circuit which turns the device on. The device is turned off upon removal of the test strip. This eliminates a need for a separate on/off circuit or patient action to turn the testing instrument on or off.

The signal producing system impregnated in the test pad matrix can be formed from different indicator systems such as 3-methyl-2-benzothiazolinone hydrazone (MBTH) and 8-anilino-1-naphthalenessulfonate(ANS) [U.S. Patent No.5,453,360 Yu], MBTH and 3-dimethylaminobenzoic acid (DMAB) [U.S. Patent No. 5,049,487 Phillips et al.], 3-methyl-2-benzothiazolinone-hydrazone-sulfonate sodium salt (MBTH-SO_4) and ANS [U.S. Patent Application 08/628,794 Douglas et al.], MBTH-SO_4 and N-(3-sulfopropyl)aniline (HALPS) [U.S Patent No. 4,396,714 Maeda et al. and U.S. Patent Application 08/628,794 Douglas et al.], MBTH-SO_4 and N- Ethyl-N-(3-sulfopropyl)aniline ALPS [U.S. Patent No. 4,396,714 Maeda et. al. and U.S. Patent Application 08/628,794 Douglas et al.]. One skilled in the art could devise an alternate indicator system. The oxidase enzyme system contained in the reagent pad produces hydrogen peroxide which is used to convert the indicator with the assistance of peroxidase which acts as the catalyst.

In the most preferred embodiment the reagents are impregnated into a porous membrane by submerging the dry membrane into a reagent dip. Excess fluid is wiped from the membrane surface and the membrane is gently dried in an oven. At this point, subsequent dipping and drying can be conducted. A preferred embodiment for a two dip process is:

MBTH-SO_4 & ALPS Formulation

A Dip	Final Concentrations
In Citrate Buffer, pH 7	0.1 M
stock A Dip	
EDTA	0.08%

mannitol	0.19%
Gantrez-S95	0.53%
Klucel 99-EF	20 uM
Crotein-SPA	7.45%

enzyme reagents

Glucose Oxidase	0.92%
Peroxidase	0.54%

B Dip

In 70% Ethanol

MBTH-SO_4	0.66%
ALPS	2.00%
SOS	0.20%

The assembly of a system kit comprised of a testing instrument and a specific number of synchronized test strips for the testing of a specific analyte can provide a simple, cost effective test method and procedure.

Figure 4 is a block diagram showing the processing operation of the testing strip and instruments. Testing instrument 21 comprises a microprocessor 41 which controls the operation of the testing instrument 21. The testing instrument 21 is activated by a switching mechanism which may comprise a mechanical ON button 34 and contacts 30 - 33 which close an appropriate circuit when the button 34 is depressed. Closing of this circuit triggers operation of the device by notifying the microprocessor 41 that a measurement reading of a positioned test strip 11 is to be performed. The test strip may be one of a number of test strips in the set, and a counter keeps track of these. Alternatively, the circuit may be closed via a fluid connection using the test sample, with the contacts 30 and 31 operating as probes provided for making contact with the test pad 12 of

the test strip 11 to thereby activate the testing instrument 21 upon detection of the sample on the appropriately positioned test strip 11.

FIGS. 5A and 5B illustrate a method of confirming the wetting of the test pad 12 to start the testing instrument 21. The test strip 11 of FIG. 5B is configured to have contacts 54 and 55 disposed on the test pad 12 thereof. The contacts 54 and 55 are spaced apart a finite distance, and are only in electrical communication by virtue of a fluid contact formed by the sample. The sample 16 is applied to the test strip 11, wetting the test pad 12 and contacts 54 and 55. The contacts 54 and 55 are in communication with contacts 30 and 31 on testing instrument 21 so when wetted this completes a circuit which starts the testing instrument 21 and begins the analysis of the sample. Of course, other activation schemes can be utilized by the invention. Two such schemes may be optical or mechanical detection of the test strip 11 in docking portion 37.

Following activation, measurement of the reaction of the sample with the reagent on the test strip 11 is effected using the optical sensor 45. Of course, the sensor itself need not be of the optical type--other expedients, such as electrochemical detection, e.g., fall within the purview of the invention. The microprocessor derives an electrical signal from the sensor 45, comprising electro-optical devices 50 and 52, and processes it to generate a detection signal indicative of analyte concentration in the tested sample. An ASIC 43 (application-specific integrated circuit) and a memory, such as RAM (random access memory) 42 or a ROM (read only memory) may be used in conjunction with the microprocessor 41, while the results of the measurement may then be displayed using LCD display 49. The results may alternatively be stored in RAM 42 for subsequent viewing or processing. The subsequent processing may be performed using the measuring instrument 21 itself, or using other devices to which the measurement results can be downloaded. One possibility in accordance with the invention is a modem link with a remote processing unit,

using, e.g., telephone lines. The information may also be downloaded for storage at an internet location or electronic bulletin board for subsequent retrieval and processing or review by medical professionals.

A calibration chip 40 is detachably connectable to the testing instrument 21 for electronic communication with the microprocessor 41. It may be any form of volatile or non-volatile memory including single use microprocessors, EPROMs or EEPROMs. Calibration chip 40 contains calibration information which is uniquely specific to the reagent provided with a particular set of test strips 11 distributed with the calibration chip. In this way, lot differences in the reagent can be compensated for using the required information and sophistication, while at the same time obviating the need for the user to enter or contribute to this information. This minimizes error and greatly facilitates use and accuracy of the testing instrument 21.

The color formed after applying the bodily fluid to the reagent test pad is proportional to the amount of analyte in the applied sample 16. The testing instrument 21, via sensor 45 and microprocessor 41, measures the change in reflectance due to the development of the specific color generated by the reagent on the test strip 11. This is either used as the input to a function which relates reflectance to analyte level or to a table which correlates reflectance value to analyte level. The function or the table must be stored within the system for it to produce and display, on display 49, a reading of the analyte level in the sample 16. While most meters in use today employ functions to convert reflectance readings to analyte concentration, this approach requires that the function be stable and well understood. The use of a look up table permits the storage of specific values for reflectance and their corresponding analyte levels. The testing instrument uses this table and interpolates between the table values to give relatively accurate readings. This is achievable in a system such as that described by this invention as the table can quickly be generated for

each reagent lot produced.

Calibration is based on the response produced by a specific lot of test strips. In this manner, there is no need to presort and test the LEDs 50 and 53, significantly reducing the cost of the sensor 45. In addition, this calibration step during manufacture allows the device to compensate for a wide area of variables normally found in reflectance systems. The specific calibration data for the test strips 11 shipped with the testing instrument can be stored in the unit's read only memory (not shown). Alternatively, a master strip can be provided for setting the calibration information for that lot of strips and the master strip can be distributed therewith. A counter may be provided to limit the testing instrument 21 to performing only a specific number of tests which correlates to the quantity of test strips 11 shipped with the device. Other limitations can be built-in, such as expiration date information pertaining to the specific lot of test strips 11, with this information being contained in the measuring instrument's ROM or in the calibration chip 40 or in the master strip.

A more traditional approach to calibration may alternatively be taken. A calibration algorithm, with several settings if necessary, could be programmed into the system if the testing instrument has a longer projected life and is to be used with multiple sets of test strips.

If a microprocessor is used for the calibration chip, the chip may be provided with its own power source for memory information retention. To prevent re-use when an EPROM or other memory device is used as the calibration chip, an optional mechanical latch 44 which would eliminate the ability to engage the calibration chip into the testing instrument 21 a second time. Similarly, when a microprocessor or EEPROM or other memory device is used, the calibration chip 40 may have its data overwritten or an indicator bit thereof be written by the microprocessor 41 following its use to prevent reuse.

The calibration information stored in the calibration chip 40 is thus downloaded to the processor memory 42, and the calibration chip is disabled, preventing re-use thereof. The calibration information contains the permitted number of test strip analyses to be performed, the number corresponding to the number of test strips provided with the kit. The calibration chip itself can then be disposed of.

Alternatively, a counter (not shown) may be provided in the calibration chip, the counter being decremented each time the chip is read. In this manner, only a limited number of readings, corresponding to the number of test strips 11 provided with the calibration chip 40, can be performed. It is also contemplated that calibration information provides and expiration date preventing use of the calibration chip and/or associated strips thereafter, or a duration can be measured after which use of the chip and/or associated strips is precluded. The duration can be commenced from time of opening a package in which the kit is provided, or from any other similar time, such as the time of first use of the calibration chip 40. The ordinarily skilled artisan will find numerous variations can be effected without departure from the spirit and scope of the invention.

The patient uses the system by removing the testing instrument from the packaging and placing it on a firm surface. The next step is to remove a test strip and insert it in the testing instrument. Inserting the test strip activates the unit, eliminating the need for a power on/off button or switch. The patient then uses either a sampler 60 (FIG. 7) from the kit or one procured separately to draw a sample of capillary blood. The kit may optionally be provided with a sampling device 62 as well. The sample is applied to the test strip, initiating a timing sequence, and the testing instrument displays the results after an appropriate time. Alternatively, the patient may first apply the blood sample to the test strip, then insert the strip into the testing instrument to activate the test cycle and read out of test results.

With the test strip and associated testing instrument, the need for a patient to purchase a costly system to conduct routine testing of body fluids is eliminated. It also eliminates the existing dependence on the customer to maintain the testing instrument and monitor/compensate for reagent lot differences. The small test pad of the present invention reduces the cost of the matrix employed and the quantity of expensive reagents needed to conduct an accurate assay using an oxidase and peroxidase chemistry. With a smaller test pad, a smaller sample volume is adequate. The system conserves the energy used and minimizes the amount of light required by the system to determine the colour change. The optics modules can be calibrated during the manufacture of the testing instrument.

CLAIMS:

1. A test strip for analysis of a bodily fluid sample and for reading in a test instrument comprising:

a strip having an opening with a test pad positioned in the opening and impregnated with a reagent system for reading in the test instrument and a handle extending from the surface of the strip on the opposite side from the opening and containing a channel for transferring the fluid sample to the test pad.

2. The test strip of Claim 1 comprising a test pad holder.

3. The test strip of Claims 1 or 2 wherein the sample size volume of the test strip is about 3 μL.

4. A test strip substantially as shown in or as described with reference to Figure 1A or 1B.

Amendments to the claims have been filed as follows

CLAIMS

1. A detection device for detecting the presence of an analyte in a sample based on a physically detectable reaction of the sample with a reagent, the device comprising:

a set of test strips, the set containing at least one test strip having an opening with a test pad positioned in the opening and impregnated with a reagent system for reading in a test instrument and a handle extending from the surface of the strip on the opposite side from the opening and containing a channel for transferring the fluid sample to the test pad;

a calibration means corresponding to the set of test strips and containing calibration information uniquely characteristic to the reagent in the set of test strips;

a housing having a docking portion for engaging at least one of the test strips;

a sensor disposed at least partially in the housing and adapted to generate an electrical signal responsive to the reaction of the sample with the reagent; and

a processor disposed at least partially in the housing and adapted to operate in accordance with the calibration means and the sensor to generate a detection signal representative of the presence of the analyte in the sample.

2. The device according to Claim 1, in which the test strip contains a test pad holder.

3. The device according to Claim 1 or 2, in which the sample size volume of the test strip is about 3μL.

4. The device according to any one of the preceding Claims, wherein the calibration means comprises a chip containing correlation information for correlating the electrical signal to the detection signal.

5. The device according to Claim 4, wherein the detection device is adapted for use with a plurality of said chips, each chip corresponding to an associated set of test strips and adapted to detachably connect to the housing.

6. The device according to Claim 5, wherein each chip is adapted for use a predetermined number of times corresponding to the number of test strips in an associated set, the predetermined number of times being tabulated by the processor, the processor disabling use of the detection device or the chip after the predetermined number of times.

7. The device of any one of Claims 4 to 6, wherein the correlation information is based on a predetermined mathematical function.

8. The device of any one of Claims 4 to 6, wherein the correlation information is based on a lookup table.

9. The device of any one of the preceding Claims, wherein the processor is adapted for disabling the use of the detection device or the chip after the predetermined date.

10. The device of any one of Claims 1 to 4, wherein the calibration means derives correlation information from a master test strip contained in the set.

11. The device of any one of the preceding Claims, further comprising a memory for storing the detection signal.

12. The device of Claim 11, further comprising a modem for downloading the detection signal from the memory to a location remote from the detection device.

13. The detection device according to any one of the preceding Claims, in which the sensor includes at least one moulded lens optic system for focusing light relative to the reagent area.

14. A detection device substantially as shown in or as described with respect to any of the accompanying drawings.

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Application No: GB 9813433.1 **Examiner:** Bob Clark
Claims searched: All **Date of search:** 26 May 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

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Int Cl (Ed.6): A61B 5/00, 5/14; B01L 3/00; G01N 21/77, 21/78, 21/86, 33/487, 33/52, 35/00

Other: Online: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
	None	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
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